UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D C 20231

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO

EXAMINER	
ART UNIT	PAPER NUMBER
	27

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

08 444,994 — Paluse et al

Jeffrey S. Parkin, Ph.D. — 1648

The MAILING DATE of this communication appears on the cover sheet with the correspondence address

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *14 Jun 2000*

2a) This action is FINAL 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-17 and 46-56* is/are pending in the application.

4a) Of the above, claim(s) *9, 10, 46, 47, and 49-56* is/are withdrawn from consideration.

5) Claim(s) is/are allowed.

6) X Claim(s) *1-8, 11-17, and 48* is/are rejected.

7) X Claim(s) *1, 11, 15, and 48* is/are objected to.

8) Claim(s) are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on is/are objected to by the Examiner.

11) The proposed drawing correction filed on is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau. (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) X Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19

18) Interview Summary (PTO-413) Paper No(s).

19) Notice of Informal Patent Application (PTO-152)

20) Other

Detailed Office Action

Status of the Claims

1. Applicants' election with traverse of Group I (claims 1-8, 11-17, and 18) in paper no. 26 is acknowledged. The traversal is based upon the premise that the inventions identified do not constitute independent and distinct groups and that an undue burden would not be placed on the Examiner if all the groups were examined concomitantly. These arguments are not deemed to be persuasive. Establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. The following items adduce a *prima facie* showing of burden: (1) The inventions of Groups I-XII are clearly directed towards independent and distinct suoject matter. Each of the identified groups employs **different viral proteins** (e.g., NP; NS1) obtained from **different viral families/subfamilies** (e.g., *Orthomyxoviridae*; *Arenaviridae*; *Retroviridae*; *Bunyaviridae*; *Adenoviridae*; *Herpesviridae*; *Paramyxoviridae*; *Lentivirinae*) and **genuses** (e.g., *Paramyxovirus*; *Morbillivirus*; *Pneumovirus*). **These viruses are all genotypically and phenotypically distinct.** Accordingly, each method will employ different viral and cellular proteins thereby necessitating separate and independent searches. Each invention will generate unique issues regarding novelty, patentability, and enablement. (2) Since the inventions disclosed *supra* are directed towards patentably distinct material, a search for one invention would not necessarily result in the identification of art that is concomitant with that required to address the issues generated by the other inventions. Applicants arguments have been thoroughly considered but are not deemed persuasive for the reasons set forth *supra* and in the original restriction requirement (paper no. 22). **The**

requirement is still deemed to be proper and is therefore made FINAL. Claims 9, 10, 46, 47, and 49-50 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 1-8, 11-17, and 48 are currently under examination.

Information Disclosure Statement

2. The information disclosure statement filed 28 September, 1998, has been placed in the application file and the information referred to therein has been considered.

Claim Objections

3. Claims 1, 11, 15, and 48 are objected to because they fail to reflect the restriction requirement set forth in the last Office action. The claims should be amended to reflect the election of Group I which is directed toward influenza virus nucleoprotein-host cell protein binding interactions. Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 and 11-17 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In*

In re Rasmussen, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Applicants have amended the claim language to include the negative limitation that the substance of interest can not be an antibody. Perusal of the specification failed to identify support for this specific negative limitation. Applicants are invited to identify those portions of the disclosure that provide direct support for the claimed limitation.

6. Claims 1-3, 11-17, and 49 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward protein binding interactions involving the influenza virus nucleoprotein and any host cell protein. However, the disclosure fails to provide sufficient support for the breadth of the claimed invention.

The legal considerations that govern enablement determinations pertaining to undue experimentation are disclosed in *In re Wands*, 8 U.S.P.Q.2d1400 (C.A.F.C. 1988) and *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows: 1) The disclosure fails to provide sufficient guidance pertaining

to those host cell proteins, that are not cell surface receptor proteins, that are capable of binding specifically to the NP.

2) The disclosure fails to provide sufficient guidance pertaining to the molecular determinants modulating these specific binding interactions. In the absence of such information, the skilled artisan can not reasonably predict which peptide fragments from either the viral or cellular protein should be employed in the screening assay.

3) The disclosure fails to provide a sufficient number of working embodiments. It appears that applicants have only identified a closely related class of molecules (designated nucleoprotein interactors or NPI) that are capable of interacting with the NP protein. No other proteins have been identified that bind to NP and meet all the claimed limitations (i.e., not a cell surface receptor).

4) The claims are of excessive breadth and are not supported by the disclosure.

When all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Correspondence

7. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1630 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

8. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 305-3227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice

Mail Service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

15 June, 2001